

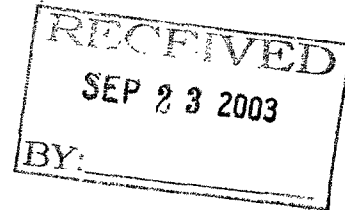
EMORD & ASSOCIATES, P.C.

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September 16, 2003



VIA UPS NEXT DAY AIR

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

***Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93***

Dear Dr. Moore:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations, Inc. retains scientific documentation supporting the statements.

1. Supplement Brand Name

Hyaluronic Acid

Ingredients

Hyaluronic acid powder (low molecular weight) (providing 9% hyaluronic acid), hypo-allergenic plant fiber added to complete capsule volume requirement.

Text of Statements of Nutritional Support

Supports synovial fluid, cartilage and skin.

Both mechanisms decrease the availability and capability of HA to maintain healthy skin and joints.

¹ The address for Pure Encapsulations, Inc. is 490 Boston Post Road, Sudbury, MA 01776.

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This polymer's functions include attracting and retaining water in the extracellular matrix of tissues, in the layers of skin, and in synovial fluid.

For skin cells, this is essential for proper cell-to-cell communication, hydration, nutrient delivery, and waste and toxin elimination.

HA also appears to support the skin by promoting healthy turnover and renewal of keratinocytes, moderating the appearance of fine lines and age spots.

For joints, HA is especially supportive of healthy lubrication and shock absorption.

Furthermore, in vitro studies indicate that HA modulates prostaglandin production, providing additional support for joint function.

The results suggest an enhancement of skin and joint health using low molecular weight HA.

A number of anecdotal and preliminary reports also indicate a positive effect on skin and joint health.

Pure Encapsulations low molecular weight Hyaluronic Acid derived from rooster comb provides support for a healthy and youthful appearance by hydrating and smoothing the skin in addition to moderating the appearance of fine lines and age spots.

Hyaluronic acid also supports joint function and comfort by promoting healthy synovial fluid composition and joint lubrication.

2. Supplement Brand Name

Petadolex®

Ingredient

Butterbur extract (28:44:1) (Petasites hybridus (root)) (standardized to contain 7.5 mg of peasin and isopetasin), riboflavin, glycerol, gelatin, sorbitol.

Text of Statements of Nutritional Support

Supports healthy cranial blood vessel function, may maintain healthy histamine release.

Petadolex®, a patented form of butterbur extracted from the root and standardized to contain a minimum of 15% petasin and isopetasin, has been studied for healthy cranial vessel support.

Petasin-containing extracts of butterbur may also help to maintain healthy histamine and cytokine release.

In one clinical trial with 60 participants, Petadolex indicated a supportive effect.

In part, the mechanism for this action may involve a supportive spasmolytic effect on smooth muscle in cranial blood vessels.

In this trial, optimal dosing of Petadolex provided significant support compared to placebo within one month.

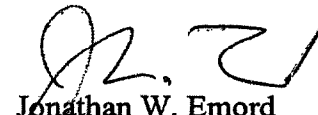
In two clinical trials, butterbur maintained healthy nasal histamine release and leukotriene activity, supporting both subjective and objective parameters.

Petadolex® provides high capacity support for healthy cranial blood vessel function.

Butterbur may also promote immune function by maintaining healthy histamine and cytokine release.

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,



Jonathan W. Emord
Claudia A. Lewis-Eng
Kathryn E. Balmford

Certification

I, Ray Hamel, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on: 9/16/03

Ray Hamel
Ray Hamel